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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,186	04/04/2005	Kazuhiro Saito	074129-0519	5576

22428 7590 10/17/2006

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EXAMINER	
TELLER, ROY R	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/530,186	SAITO ET AL.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment, received 8/2/06.

Claims 16-29 are pending.

Claim Rejections - 35 USC § 112

Claim 16 stands/is rejected under 35 USC 112, second paragraph for the reasons of record which are restated below.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 recites a sustained release preparation which gradually releases for a "long term" and a "short term". This is vague and indefinite as to the length of the envisioned long term and short term use of the preparation.

All other claims depend directly or indirectly from the rejected claim and are, therefore, also rejected under 35 USC 112, second paragraph.

Applicant's response has been carefully considered but was not found persuasive.

Applicant contends that the instant specification thoroughly describes the terms "long term" and "short term". However, the examiner contends that the length of the envisioned long term and short term use of the preparation is not defined in the claim. The examiner suggests incorporating the limitations of claim 19 and 20 into claim 16 to adequately define long term and short term.

Double Patenting

Claims 16-29 are/stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting for the reasons of record which are restated below.

Claims 16-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7, 19, 20, 23, and 27 of copending Application No.10/498,215. Although the conflicting claims are not identical, they are not patentably distinct from each other because the sustained release composition contains the same lactic acid polymer molecular weight averages, same peptide equivalent and is used to prevent or treat the same diseases .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's response has been carefully considered but was not found persuasive.

Applicant contends that the cited references are different from each other because the instant invention is drawn to improving a blood concentration pattern of a GnRH agonist, whereas the cited reference is directed to improving dispersion of one kind of microcapsule. However, the examiner contends that the sustained release composition of the instant invention and the cited reference contain the same lactic acid polymer molecular weight averages, the same peptide equivalent and is used to prevent or treat the same diseases .

Claim Rejections - 35 USC § 103

Claims 16-29 are/stand rejected under 35 USC 103(a) for the reasons of record which are restated below.

Claims 16-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al (USPN 6,113,943) in view of Hutchinson (USPN 5,889,110).

The instant invention is drawn to a sustained release preparation comprising a combination of first microcapsules which release a GnRH agonist (or LHRH) for a long term and second microcapsules which release a GnRH agonist (or LHRH) for a short term.

Such compounds having GnRH activity include, specifically, leuprorelin, buserelin and goserelin, see, i.e, for example, specification, page 2, lines 2-4.

Okada teaches a sustained release preparation comprising a polymer of lactic acid having an average molecular weight of about 25,000 to about 60,000 and a physiologically active peptide, wherein the peptide is leuprorelin, leuprorelin acetate, buserelin or goserelin, and which releases the physiologically active substance over a period of at least five months, see, ie., abstract, column 1-2, claims 1 and 11. Okada discloses when the physiologically active substance is leuprorelin or leuprorelin acetate, a sustained release preparation is useful for diseases such as prostatic cancer and breast cancer, see, i.e., for example, column 20.

Okada does not teach a short term use of the sustained release preparation.

Hutchinson teaches extended release pharmaceutical compositions, which suitable pharmacologically active peptides such as LHRH, leuprorelin, buserelin, and goserelin, see, i.e., for example, abstract, column 2, claim 4 and 14, . Hutchinson discloses experiments for the

release of goserelin over relatively short periods of time of 5-7 weeks, see, i.e., for example, column 26. Huttchinson teaches a lactide/glycolide co-polymer having a weight average molecular weight of about 15,000 Da, see, i.e., for example, column 30.

Based upon the beneficial overall teachings provided by Okada with respect to Hutchinson , Hutchinson discloses similar formulations can be manufactured using, in place of goserelin, either leuprorelin or buserelin and continuous release over a relatively long period of time of up to 6 months, see, i.e, for example column 25 and 22. Okada discloses the dose of the sustained release preparation per administration for one month in terms of a physiologically active range, see, i.e, for example, column 20.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's response has been carefully considered but was not found persuasive.

Applicant contends that the cited references are directed to a single preparation. However, the examiner contends that based upon the beneficial overall teachings provided by Okada with respect to Hutchinson , Hutchinson discloses similar formulations can be manufactured using, in place of goserelin, either leuprorelin or buserelin and continuous release over a relatively long period of time of up to 6 months, see, i.e, for example column 25 and 22. Okada discloses the dose of the sustained release preparation per administration for one month in terms of a physiologically active range, see, i.e, for example, column 20.

Conclusion

All claims are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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10/11/06
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Cecilia J. Tsang
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